

AMENDMENTS TO THE CLAIMS

LISTING OF CLAIMS:

1. (Currently amended): A method of The use of lycopene in the manufacture of a composition for the primary and secondary prevention, incidence risk reduction, coadjuvant treatment or treatment of non-cancerous symptoms and/or pathologies, which are associated with, favored by or caused by androgen signalling, or which are sensitive to a reduction of androgen signalling comprising admixing an effective amount lycopene with a conventional carrier material.
2. (Currently amended): A method according to The use as in claim 1 wherein the composition comprises of lycopene in combination with vitamin E.
3. (Currently amended): A method according to The use as in claim 1 wherein the composition comprises or 2 of lycopene in combination with vitamin E and/or vitamin C.
4. (Currently amended): A method according to claim 1 wherein the composition comprises The use as in any one of claims 1 to 3 of lycopene in combination with one or more compounds selected from: silymarin, silybin or equimolar amounts of derivatives, isosilybin or equimolar amounts of derivatives, silydianin or equimolar amounts of derivatives, silychristin or equimolar amounts of derivatives, saw palmetto or equimolar amounts of derivatives, free fatty acids (lauric acid, oleic acid, myristic acid, palmitic acid) or equimolar amounts of derivatives, phytosterols (sistosterol, campesterol, stigmasterol, cycloartenol, sitostanol, campestanol) or equimolar amounts of derivatives (long-chain fatty acid acyl ester, ferrulate ester, glycosides), genistein aglycone, genistein glucosides, genistein sulfates, genistein glucuronides, apigenin, quercetin or equimolar amounts of derivatives (quercetine glucosides, quercetin glucuronides, quercetine sulphates, methylquercetin (isohamnetin 3'-O-methylquercetin), tamarixetin(4'-O-methylquercetin)), myricetin, kampferol, resveratrol or equimolar amounts of derivatives, Curcumin (effects of *Curcuma Longa*) or equimolar amount of derivatives thereof (demethoxy-curcumin, bis-

demethoxycurcumin, sodium curcumionate, bis-demethylcurcumin, tetrahydrocurcumin, hexahydrocurcumin, diacetylcurcumin, triethylcurcumin) and/or equimolar amount of 1st main components components (curcumin (diferuloylmethane), demethoxycurcumin, bisdemethoxycurcumin) and/or derivatives thereof (glucuronides, sulfates), flufenamic acid, geldanamycin, extract of *Stephania hernandifolia* and/or [[or]] one or more of its components (e.g. 4-demethylhasubanonine, epistephanine), extract of *Myrica rubra* and/or one or more derivatives thereof and/or one or more of its components being diarylheptanoids (Quercetin, myricanone, myricanol, and myricetin) named acerogenin and their glycosides named aceroside and/or derivatives thereof, astaxanthin,  $\beta$ -carotene,  $\beta$ -cryptoxanthin, (-)-epigallocatechin gallate (EGCG) or (-)-epicatechin gallate (ECG) or equimolar amounts of derivatives, lutein, rhizoxin, palmitoyl rhizoxin, all-trans retinol, retinoic acids (all-trans retinoic acid and/or 13-cis retinoic acid and/or 9-cis retinoic acid) and/or one or more derivatives thereof (4-hydroxyphenylretinamide or retinyl esters such as all-trans retinyl acetate); all-trans retinyl acetate, all-trans retinol palmitate, vitamin D2 (ergocalciferol), vitamin D3, (cholecalciferol), 1 $\alpha$ , 25-dihydroxyvitamin D3, 25-hydroxyvitamin D3, 1 $\alpha$ , 24R, 25-trihydroxyvitamin D3, 24, 25-dihydroxyvitamin D3, zeaxanthin, carnosic acid, carnosol, depudecin, eponemycin, dihydroeponemycin, epoxomicin, ergosterol, fisetin, fumagillin, lactacystin, luteolin, motuporamine C, ovalicin, radicicol, squalamine, isoliquiritin, isoliquiritigenin, very-long-chain omega-3 fatty acids (eicosapentaenoic acid [C20: 5, omega-3], decosahexaenoic acid [C22: 6, omega-3], polyunsaturated  $\omega$ -3 fatty acids), shark cartilage extract, glucosinolate derivatives (Methylsulfinylalkyl glucosinolates (1-methylsulfinylmethyl glucosinolate, 2-methylsulfinylethyl glucosinolate, 3-methylsulfinylpropyl glucosinolate (glucoiberin), 4-methylsulfinylbutyl glucosinolate (glucoraphanin), 5-methylsulfinylpentyl glucosinolate (glucoalysin), 6-methylsulfinylhexyl glucosinolate, 7-methylsulfinylheptyl glucosinolate, 8-methylsulfinyloctyl glucosinolate, 9-methylsulfinylnonyl glucosinolate, 10-methylsulfinyldodecyl glucosinolate) or allyl glucosinolate (sinigrin) or indol-3-ylmethyl glucosinolate (glucobrassicin) or derivatives thereof (N-methoxyindol-3-ylmethyl glucosinolate (neoglucobrassicin), 4-hydroxyindol-3-ylmethyl glucosinolate (4-OH glucobrassicin), 4-methoxyindol-3-ylmethyl glucosinolate (4-CH<sub>3</sub>O glucobrassicin)) or phenylethyl glucosinolate (gluconasturtiin) or 3-butetyl glucosinolate (gluconapin)),

or isothiocyanate derivatives (Methylsulfinylalkyl isothiocyanate (1-methylsulfinylmethyl isothiocyanate, 2-methylsulfinylethyl isothiocyanate, 3-methylsulfinylpropyl isothiocyanate, 4-methylsulfinylbutyl isothiocyanate (sulforaphane), 5-methylsulfinylpentyl isothiocyanate, 6-methylsulfinylhexyl isothiocyanate (6-HITC), 7-methylsulfinylheptyl isothiocyanate, 8-methylsulfinyloctyl isothiocyanate, 9-methylsulfinylnonyl isothiocyanate, 10-methylsulfinyldecyl isothiocyanate) or allyl isothiocyanate, indole-3-ylmethylisothiocyanate, N-methoxy indole-3-ylmethylisothiocyanate, 4-hydroxy indole-3-ylmethylisothiocyanate, 4-methoxy indole-3-ylmethylisothiocyanate, 3-Indolemethanol, phenylethyl isothiocyanate (PEITC), 3-but enyl isothiocyanate).

5. (Currently amended): A method according to claim 1 [[The use in any one of claims 1-4]], in which said symptom or pathology is polycystic ovary syndrome, hyperandrogenic chronic anovulation, female infertility, ovarian hyperstimulation syndrome, amenorrhea, oligomenorrhea, accumulation of abdominal fat, insulin resistance, hyperinsulinemia, type 2 diabetes mellitus, hypertension, hirsutism, feminine acne, alopecia, menstrual disorder, hyperandrogenism, SAHA syndrome, congenital adrenal hyperplasia (CAH), stress induced imbalance of androgen signalling or benign prostatic hyperplasia.

6. (Currently amended): A method according to ~~The use as in~~ claim 5, in which said symptom or pathology is polycystic ovary syndrome, hyperandrogenic chronic anovulation, female infertility, ovarian hyperstimulation syndrome, amenorrhea, oligomenorrhea, accumulation of abdominal fat, insulin resistance, hyperinsulinemia, hirsutism, feminine acne, alopecia, menstrual disorder, hyperandrogenism, SAHA syndrome, congenital adrenal hyperplasia (CAH) or benign prostatic hyperplasia.

7. (Currently amended): A method according to ~~The use as in~~ claim 6, in which said symptom or pathology is polycystic ovary syndrome, obesity, insulin resistance, hyperinsulinemia, type 2 diabetes mellitus, hypertension, hirsutism, feminine acne, menstrual disorder, hyperandrogenism or benign prostatic hyperplasia.

8. (Currently amended): A method according to ~~The use as in~~ claim 7, in which said pathology is feminine acne.

9. (Currently amended): A method according to ~~The use as in~~ claim 7, in which said pathology is hirsutism.

10. (Currently amended): A method according to ~~The use as in~~ claim 7, in which said pathology is type 2 diabetes mellitus.

11. (Currently amended): A method according to ~~The use as in~~ claim 7, in which said pathology is polycystic ovary syndrome.

12. (Currently amended): A method according to ~~The use as in~~ claim 7, in which said pathology is benign prostatic hyperplasia.

13. (Currently amended): A method according to ~~claim 1 The use in any one of claims 1 to 12~~ wherein the composition is a solid or liquid galenical formulation, a dietary composition or an animal feed composition.

14. (Currently amended): A method according to ~~The use as in~~ claim 13 wherein a dosage unit of said solid galenical formulation contains from about 0.25 mg to about 50 mg of lycopene.

15. (Currently amended): A method according to ~~The use as in~~ claim 14 wherein a dosage unit of said solid galenical formulation further contains from about 10 mg to about 1000 mg of vitamin E.

16. (Currently amended): A method according to ~~claim 14 The use as in claim 19 or 22~~ wherein a dosage unit of said solid galenical formulation further contains from about 50 mg to about 1000 mg of vitamin C.

17. (Currently amended): A method according to ~~claim 14 wherein the composition comprises~~ ~~The use as in any one of claims 14 to 16 of~~ lycopene in combination with vitamin E, vitamin C and resveratrol in ~~the manufacture of~~ a solid galenical formulation for the coadjuvant treatment of feminine acne.

18. (Currently amended): A method according to claim 14 wherein the composition is in the form of ~~The use as in any one of claims 14 to 16 in the manufacture of~~ a solid galenical formulation for the prevention of polycystic ovary syndrome containing lycopene in combination with vitamin E, vitamin C, and silymarin in one dosage unit.

19. (Currently amended): A method according to ~~The use as in~~ claim 13 wherein said liquid galenical formulation contains from about 0.1 mg to about 100 mg of lycopene per ml.

20. (Currently amended): A method according to ~~The use as in~~ claim 17 wherein said liquid galenical formulation further contains from about 10 mg to about 300 mg of vitamin E per ml.

21. (Currently amended): A method according to ~~The use as in~~ claim 20 [[or 23]] wherein said liquid galenical formulation contains from about 50 mg to about 100 mg of vitamin C per ml.

22. (Currently amended): A method according to ~~The use as in~~ claim 13 wherein said dietary composition or animal feed composition contains from about 0.025 mg to about 5 mg of lycopene per g.

23. (Currently amended): A method according to ~~The use as in~~ claim 21 wherein said dietary composition or animal feed composition further contains from about 1.5 mg to about 30 mg of vitamin E per g.

24. (Currently amended): A method according to ~~The use as in~~ claim 21 [[or 24]] wherein said dietary composition or animal feed composition further contains from about 5 mg to about 50 mg of vitamin C per g.

25. (Original): A method of prevention or treatment of symptoms or pathologies associated with androgen signalling, which comprises administering to a subject (mammal or non-mammal, human or pet including birds and fish, or mammal or

non-mammal farm animal) in need of such treatment for therapy or prophylaxis an effective amount of lycopene.

26. (Original): A method as in claim 25 wherein about 0.25 mg to about 50 mg of lycopene are administered per day to a human adult.

27. (Original): A method as in claim 26 wherein about 1 mg to about 30 mg of lycopene are administered per day to a human adult.

28. (Currently amended): A method as in claim 25 ~~any one of claims 25 to 27~~ wherein, additionally, about 15 mg to about 600 mg of vitamin E are administered per day to a human adult.

29. (Currently amended): A method as in claim 25 ~~claims 25 to 28~~ wherein, additionally, about 50 to about 1000 mg of vitamin C are administered per day to a human adult.

30. (Original): A method of treating non-cancerous symptoms and/or pathologies sensitive to lycopene which comprises administering to a mammal, mammal or non-mammal pets including birds and fish, or mammal or non-mammal farm animal in need of such treatment an amount of lycopene which leads to a reduction of androgen signalling.

31. (Original): The method according to claim 30, wherein an amount of lycopene is administered which results in a plasma concentration of 0.01 to 6  $\mu$ M.